UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,181	06/02/2006	Roberts Cynthia	OSU 0011 PA/41096.27	2245

23368 7590 07/07/2010

DINSMORE & SHOHL LLP
FIFTH THIRD CENTER, ONE SOUTH MAIN STREET
SUITE 1300
DAYTON, OH 45402-2023

EXAMINER	
LIPITZ, JEFFREY BRIAN	

ART UNIT	PAPER NUMBER
3769	

MAIL DATE	DELIVERY MODE
07/07/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,181	CYNTHIA ET AL.	
	Examiner	Art Unit	
	JEFFREY B. LIPITZ	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 7, 8, 11-19, 24-27, 30- 32, 34 and 38-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 7, 8, 11-19, 24-27, 30- 32, 34 and 38-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 8, 11-19, 24-27, 30-32, 34, 38-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. How does a user or the processor select an ablative surgical algorithm or update the algorithm? In other words, on what basis does selecting and updating occur? Why are some data included or excluded when performing these steps? How does the processer weigh the importance of particular data?

Claims 1, 7, 8, 11-19, 24-27, 30-32, 34, 38-52 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A laser to ablate corneal tissue, a processor or functional equivalent, a memory of functional equivalent, a data receiver or functional equivalent, a means for acquiring pre- and post-operative measurements are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Examiner will now a provide a list of questions related to independent claim 1 that should help to further clarify the basis of this rejection. How is

this method an implementing method for customizing ablative surgery when there is no ablative surgery claimed? How can any data be received before measurements are made? What is receiving the data? How is any data, correlation or model stored without a memory? How can post-perturbation data be received without "perturbing" (e.g. ablating, cutting, scraping, etc...) the cornea? How can the steps of selecting and updating occur without a processor?

Claims 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims recite limitations which were not described in the specification in such a way to be reasonably understood by one of ordinary skill in the art. What's a field of a data structure? How does an interface communicate data? To what is an interfacing communicating data?

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite elements used in steps that are inherent to previously described steps. The corneal data, correlation data and algorithms must be executed by a computer component. It is also unclear what an

interface for communicating is intended to include/exclude in its scope. What is a field suppose to include/exclude in its scope?

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 7, 8 and 25-27, 38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims are not necessarily performed by a machine and do not transform underlying subject matter. Therefore, they constitute non-statutory subject matter in view of See *In re Bilski*, 88 USPQ 2d 1385 (2008).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 8, 11-19, 24-27, 30-32, 34, 38-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Dai et al. (20050096640), hereinafter Dai.

Regarding claims 1, 7, 8, 11, 12-19, 25-27, 41-48, 51, Dai teaches taking into account pre-operative data, such as data collected from wavefront measurements (210; Figure 6) as well as "real ablation data (270), which includes data collected after the

microkeratome is used to cut the corneal flap (Paragraph [0219]). Dai teaches an approach to modeling limitations on the system/method so that adjustment or adaptation of the ablation algorithm can be obtained (Summary of the Invention). Dai teaches providing a processor and memory to receive and store data, as well as ablation tables (Paragraph [0070]). Dai teaches that the wavefront parameters that are correlated with other parameters include spot identification factors, accommodation factors and reconstruction factors (Paragraphs [0108]-[0118]). Dai teaches a plurality of error models that are fit into a larger model of surface shape (Paragraphs [0095]-[0106]).

Regarding claim 24, a corneal data receiver and a data integrator are necessary components to accomplish the method of Dai.

Regarding claims 30-32, 38, 40, 49 and 40, these claims contain limitations that use elements that are inherent to previously rejected steps. The "interfaces" and a data structure are structural and functional equivalents. "Fields" of a data structure have no patentable weight, since any data storage element will have to store data in a certain number of bits. How many bits does it take to store post-perturbation data? How is it "separated" into its own field? What is a field intended to include? Examiner interprets a memory and a data structure for holding data as structural and functional equivalents.

Regarding claims 34 and 52, Dai teaches receiving corneal measurements (210; Figure 6), which inherently would require instructions to have been given to obtain these measurements. Likewise, Dai teaches using an algorithm (220) to come up with treatment tables (250), and then a predicted or ideal post-operative ablation (260).

These algorithms are then modified by error data (270), as well as post-perturbation data, which in this case includes data collected after a flap has been formed (270).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Huang (20050107775) teaches a method and apparatus for controlling ablation in eye surgery. Huang teaches receiving measurements, selecting algorithms, and a plurality of correlations.

Rajan (5891131) teaches a method and apparatus for automated simulation and design of corneal refractive procedures (Figure 2). Rajan teaches all but perturbing the cornea.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEFFREY B LIPITZ/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769